REMARKS

In response to the Office Action of October 22, 2002, applicant respectfully requests reconsideration and allowance of the claims in their redrafted form.

By this amendment applicant has amended pages 6 and 10 of her specification to correct an inadvertent typographical error in the spelling of "well". Any inconvenience to the Examiner is sincerely regretted.

Applicant has also redrafted claim 1-8 and new claims 9-16 to more clearly define her invention. Old claim 8 has been withdrawn from the application without prejudice to renew. In redrafting the claims applicant has included the helpful comments and suggested language set forth by the Examiner on pages 2 and 3 of the Office Action.

It is respectfully submitted that the preamble of old claim 9 has been amended to avoid any confusion with regard to what the method is intended to test. Claim 9 now recites that the invention is to test for HLE of the plasma membrane and not the HLE receptors.

Step D of claim 1 has been amended in new claim 9 to include the language suggested by the Examiner on page 2 of the Office Action.

Applicant has also added new step E to generic claim 9 using the language suggested by the Examiner to insure that the claim is complete.

In original claim 1, fitfth line of step C. the "which" describes "the material". However, the Examiner ins correct that the material does not directly interact with the HLE receptors. It is included in the immunoreagent which itself interacts with the HLE on the plasma membranes. As a result of such interaction the material produces a characteristic physical change that can be monitored. It is hopeful that the language of new claim 9 overcomes any confusion.

Applicant has also changed "in" to –on- in describing the interaction with HLE "on" the plasma membranes.

In redrafted claim 10, phenomena" has been used instead of "states". Also new claim 15 which corresponds to old claim 6 is now properly dependent on claim 14 and has proper antecedent basis for "said reporter or indicator molecule" in claim 14.

New claim 16 is believed to be free of any confusion in tha the members of the group are indented and set forth as alternate members from each other.

It is therefore submitted that new claims 9-16 are in compliance with the first paragraph of 35USC 112 and are no longer confusing.

With respect to the adequacy of the description of the immunoreagents, applicant submits that her specification is more than adequate to convey to one skilled in this art which immunoreagents would be suitable for practicing the method as claimed. Also, on pages 6 and 7 of the Office Action the Examiner has rejected old claims 1-8 as containing subject matter not described in the specification in such a way as to reasonably convey to one skilled in the arthow to make and use her invention with respect to the disclosure of diseases and pathologic phenomena.

Detection of HLE is used for differential diagnosis and staging of many myelogenous disorders including leukemia and lymphoma. The promoter fro the HLE gene also stimulates activation of certain oncogenes (c-myb). Therefore, detection of HLE has become an important tool for the hematopathologist. Current clinical laboratory methods for detecting HLE involve staining cells on mounted slides. The present invention is the first of its kind for detecting HLE on the cell surface, and this allows the hematopathologist for the first time to monitor stage differentiation by HLE.

Applicant respectfully submits that with respect to both the disease or pathologic phenomena as well as the immunoreagents employed, it must be remembered that her disclosure is not directed to the ordinary layperson but to one skilled in the art to which the invention pertains. Moreover, applicant's invention is not directed to a cure or even a detection of a disease, but to a method for monitoring the progression of just those diseases or pathologic phenomena that corrolate with surface density of HLE associated with plasma membranes of lymphocytes and mononuclear phagocytes.

Applicant has set forth on page 6, lines 3 et seq., of her specification that her invention allows the determination of disease progression in pathologic state resulting from microbial organisms, transplantation, autoimmunity, cancer HIV infection and the like. While the method of the invention is particularly well-suited for monitoring the progression of AIDS it is not the intention of applicant that her invention be limited to such conditions. One skilled in the art would have no difficulty in knowing where

applicant's method could be used.

With respect to the immunoreagents, applicant has set forth on page 6, lines 21 et seq., that the HLE specific immunoreagent for use in the method of this invention is composed of binding proteins which interact with one or more of the characteristic domains of membrane surface HLE. Applicant therefore respectfully submits that it would be unduly limiting to require her to limit her invention to just the preferred embodiment disclosed or even to antibodies. One skilled in the art after reading applicant's specification and with the knowledge gained therefrom, would have no difficulty in the selection of immunoreagents or in the kinds of diseases or pathologic phenomena for which the method would be applicable. Withdrawal of the rejection under 35 USC 112, first paragraph, is respectfully requested.

If the Examiner believes that the immunoreagent should be defined in the claims as a binding protein which interacts with one or more of the characteristic domains of membrane surface HLE, applicant would have no objection to such a definition. .

For each of the foregoing reasons applicant submits that the claims in their redrafted form are in condition for allowance. Early, favorable action is therefore respectfully requested.

If a personal interview with the Examiner would advance the prosecution of this application, applicant's attorney would be pleased to meet with the Examiner to resolve any outstanding issues.

I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED WITH THE UNITED STATES POSTAL SERVICE AS FIRST CLASS MAIL IN AN ENVELOPE ADDRESSED TO: COMMISSIONER OF PATENTS AND TRADEMARKS, WASHINGTON, D.C. 20231, ON March 24, 2003

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DATE: March 24, 2003

Respectfully submitted

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-22-986-5801

MARKED-UP VERSION OF PAGE 6 OF THE SPECIFICATION

The HLE on the plasma membrane of lymphocytes and mononuclear phagocytes is fairly [will] well characterized. Thus, the epitopes characteristic of receptor structures, and their ability for accessible binding to an immunoreagent (e.g.antibody mimic), is simply a matter of choice. In one of the preferred embodiments of this invention, the immunoreagent suitable for use in the method of this invention is capable of immunochemical interaction with at least one of the catalytic triad of the HLE membrance surface proteins and the lipid interactive amino acids of the HLE membrane surface proteins. This catalytic triad of HLE (domain 1) is composed of amino acids His (41), Asp (88), and Ser (173). Lipid-interactive amino acids of the HLE (domain 2) is composed of amino acids Phe (170), Ala (187), and Arg (191); and these amino acids are proximal to the catalytic triad. The HLE specific immunoreagent for use in the diagnostic test method of this invention, thus, comprises binding proteins which interact with one or more of the characteristic domains of

MARKED-UP VERSION OF PAG 10 OF THE SPECIFICATION

The HLE receptors on the plasma membrane of lymphocytes and mononuclear phagocytes are fairly [will] well characterized. Thus, the epitopes characteristic of receptor structure, and their availability for accessible binding to an immunoreagent (e.g. antibody mimic), is simply a matter of choice. In one of the preferred embodiments of this invention, the immunoreagent suitable for use in the method of this invention is capable of immunochemical interaction with at least one of the catalytic triad of the HLE membrane surface proteins and the lipid interactive amino acids of the HLE membrane surface proteins. This catalytic triad of HLE (domain 1) is composed of amino acids His (41), Asp (88), and Ser (173). Lipid-interactive amino acids of the HLE (domain 2) is composed of amino acids Phe (170), Ala (187), and Arg (191); and, these amino acids are proximal to the catalytic triad. Similarly, the CD4 and chemokine receptors on the plasma membrane of lymphocytes and mononuclear phagocytes are also well-characterized. "